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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JAMES J. BARRY and SEAN GILLIGAN

Appeal 2009-010186
Application 09/842,833
Technology Center 3700

Decided:[1] July 29, 2009

Before: WILLIAM F. PATE, III, LINDA E. HORNER and MICHAEL W. O'NEILL, *Administrative Patent Judges*.

PATE, III, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

STATEMENT OF CASE

Appellants appeal under 35 U.S.C. § 134 from a rejection of claims 1, 3, 5-11 and 24-32. Claims 2, 4, and 15-23 have been cancelled, and claims 12-14 have been withdrawn. App. Br. 4. We have jurisdiction under 35 U.S.C. § 6(b).

The claims are directed to a coated implant delivery system. Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. A coated implant delivery system comprising:
>
> an implant delivery device with a first end, a second end, and an inner lumen,
>
> the first end having a releasable implant retention region,
>
> the releasable implant retention region having an accessible surface,
>
> the accessible surface of the releasable implant retention region having an implant adhesion-resistant treatment;
>
> a releasable implant having an implant coating,
>
> the releasable implant releasably positioned in physical communication with the implant adhesion-resistant treatment on the accessible surface of said releasable implant retention region,
>
> the implant coating facing the implant adhesion-resistant treatment on the releasable implant retention region
>
> wherein the implant adhesion-resistant treatment prevents the implant coating from being stripped from an implant surface.

The prior art relied upon by the Examiner in rejecting the claims on appeal is:

Savin	US 4,950,227	Aug. 21, 1990
Wang	US 5,902,631	May 11, 1999
Michal	US 6,287,285 B1	Sep. 11, 2001

Claims 1, 3, 7, 11 and 24-32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Savin and Michal. Ans. 3.

Claims 5, 6 and 8-10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Savin, Michal and Wang. Ans. 4.

ISSUE

Claims 1, 3, 7, 11 and 24-32 are argued as a group. App. Br. 9-15. We select claim 1 as the representative claim, and claims 3, 7, 11 and 24-32 stand or fall with claim 1. 37 C.F.R. § 41.37(c)(1)(vii). Claims 5, 6 and 8-10 are also argued as a group. App. Br. 16. Appellants' argument regarding claims 5, 6 and 8-10 is based solely upon their dependence from claim 1.

Appellants contend that Savin fails to disclose an implant adhesion-resistant treatment on the accessible surface of the delivery device. App. Br. 9; *contra* Ans. 3. Appellants also note that Savin does not disclose an implant having a coating on the surface in contact with the delivery device, i.e., the inner surface. App. Br. 9. The Examiner does not contend that Savin discloses the claimed coating on the inner surface of the implant, but instead relies upon Michal for a teaching that this feature is known in the art. Ans. 3. Appellants contend, however, that Michal only teaches that it was known in the art to provide a coating on the outside surface of the implant. App. Br. 10-15.

In light of these contentions, we must determine whether the Appellant has established that the Examiner erred in rejecting claim 1 under 35 U.S.C. 103(a) as being unpatentable over Savin and Michal.

FINDINGS OF FACT

1. Savin discloses a stent delivery system 10 wherein a stent 16 formed of wire loops is fixed about a balloon 14 by two overlying retaining sleeves 18, 20. Col. 4, ll. 3-16; fig. 1.
2. In order to aid release of the stent from the sleeves 18, 20, a lubricating solution can be provided between the balloon 14 and the sleeves 18, 20. Savin, col. 4, ll. 55-57.
3. The stent may have a lubricious or hydrophilic coating. Savin, col. 2, ll. 49-50, col. 7, ll. 43-44.
4. Michal discloses various coatings which may be applied to a variety of medical devices. In particular, Michal discloses that a therapeutic, diagnostic, or hydrophilic coating can be applied to an intravascular stent. Col. 12, ll. 8-27; figs. 10-12.
5. Michal's preferred method of coating a device is by dipping it. Col. 13, ll. 17-18. This would result in a coating on all surfaces of the device, including the inside, as depicted, for example, in figure 12.
6. Wang discloses coatings for medical devices having lubricity gradients. Abstract.

PRINCIPLES OF LAW

"35 U.S.C. § 103 forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such

that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.'" *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of skill in the art, and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). *See also KSR*, 550 U.S. at 407.

A patent applicant is free to recite features of an apparatus either structurally or functionally. *See In re Swinehart*, 439 F.2d 210, 212 (CCPA 1971) ("[T]here is nothing intrinsically wrong with [defining something by what it does rather than what it is] in drafting patent claims."). Yet, choosing to define an element functionally, i.e., by what it does, carries with it a risk. *In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997). As stated in *Swinehart*:

> [W]here the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.

439 F.2d at 213.

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the

prior art in terms of structure rather than function. *See e.g., In re Schreiber*, 128 F.3d at 1477-78.

ANALYSIS

The subject matter of claim 1 would have been obvious because it involves only the combination of familiar elements to achieve predictable results. While Savin does not disclose the specifics of how the coating is applied to the stent, it is clear from Michal that stents having coatings applied to their inside surface are known in the art. Fact 5. In fact, the damage of such coatings is the problem Appellants seek to overcome. Spec. 1-2. Appellants do not contest that a lubricating solution constitutes "implant adhesion-resistant treatment." Appellants only contest that this lubricating solution is not applied to the surface of the delivery device that receives the implant. App. Br. 9-10. However, if a lubricating solution placed between the sleeves 18, 20 and the balloon 14 were to be effective at aiding release of the stent, the solution must be applied at least in the region where the sleeves slide over the balloon, i.e., "D" in figure 1. The stent, having an open-celled structure (*See* Fact 1), would have the lubricating solution passing therethrough. Since the implant is retained in this region, this results in a surface of the balloon having an adhesion-resistant treatment, lubrication, in physical communication with the releasable stent. That surface is in a facing relationship with the inside surface of the stent.

Both the Examiner and Appellants agree that Savin is silent regarding whether that inside surface of the stent is coated. *See* Fact 3. Appellants' argument that Michal only coats the outside surface of the stent is inaccurate. Although Michal may primarily be concerned with coating the

outer surface of the stent, it is clear that Michal also coats the inner surface. Fact 5. The fact that Michal does not explicitly state any particular reason, other than presumably ease of manufacture, for coating this surface, does not establish that the Examiner's conclusion that it would have been obvious to use Michal's stent on Savin's delivery system was in error. It is not necessary for the prior art to serve the same purpose as that disclosed in Appellants' Specification in order to support the conclusion that the claimed subject matter would have been obvious. *See In re Linter,* 458 F.2d 1013, 1016 (CCPA 1972).

The system resulting from the combination of Savin and Michal, having less friction in certain areas of the stent, would serve to perform the recited function of preventing the implant coating from being stripped from an implant surface. Again, it is not necessary to sustain a conclusion of obviousness that Savin and Michal address the same problem as Appellants. The combination yields the structure recited in claim 1 even though Savin's lubricating solution and Michal's coating may be applied for different reasons. *See* Facts 2, 4 and 5. Appellants have not provided any evidence to establish that the Savin system, as modified with the Michal stent, would not perform the recited function of preventing the implant coating from being stripped from an implant surface. *See Swinehart*, 439 F.2d at 213.

CONCLUSION OF LAW

On the record before us, Appellants have not established that the Examiner erred by rejecting claim 1 under 35 U.S.C. 103(a) as being unpatentable over Savin and Michal. Since no substantive arguments are presented that are specific to claims 5, 6 and 8-10, Appellants have also

failed to establish that the Examiner erred by rejecting these claims under 35 U.S.C. 103(a) as being unpatentable over Savin, Michal and Wang.

DECISION

For the above reasons, the Examiner's rejection of claims 1, 3, 5-11 and 24-32 is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). See 37 C.F.R. § 1.136(a)(1)(iv) (2007).

AFFIRMED

mls

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